MAY 2 3 2001

K010576

510(k) Summary

Proprietary name: Monarch Spine System

Common Name: Spinal Fixation System

Classification Name and Reference: Spinal interlaminal fixation orthosis, §888.3050
Pedicle screw spinal fixation §888.3070

Proposed Regulatory Class: Class II

Device Product Code: 87/KWP, 87/MNH, 87/MNI

The Monarch Spine System is both a rod-based and plate-based system designed to interface with various spinal anatomies. The plate-based system consists of pedicle screws, spine plates, ISOLA Modular Cross Connector (MCC) transverse connectors, J-hooks, washers, and nuts. The rod-based system consists of spinal rods, pedicle screws, polyaxial screws, caps, various slotted connectors, open and closed hooks, various rod-to-rod connections, ISOLA Modular Cross Connector (MCC) transverse connectors, and ISOLA EZ-X transverse connectors.

The Monarch Spine System is manufactured from implant grade titanium alloy that conforms to ASTM standard F-136.

The Monarch Spine System is substantially equivalent to the TiMX Low Back System previously cleared in K981274 and K981714, the Moss Miami Spinal System previously cleared in 510(k) K955348 and K983583, and the ISOLA System previously cleared in 510(k) K980485.The substantial equivalence is based upon an equivalence in design, materials, manufacturing methods, intended use, and relative indications and contraindications.

The Monarch Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Monarch Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Monarch Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The Monarch Spine System Dual Rod Connectors can be used to connect Monarch Spine System Rods to rods of other DePuy AcroMed 4.75mm, 5.5mm, and 6.35mm diameter rod systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy AcroMed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K010576
Trade Name: Monarch Spine System
Regulation Number: 888.3050 and 888.3070
Regulatory Class: II
Product Codes: MNI, KWP and MNH
Dated: February 26, 2001
Received: February 27, 2001

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010576

Device Name:

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(per 21 CRF 801.109)

for Mark N Milhem
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010576

(Optional Format 1-2-96)